The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

PRIORITY DOCUMENT

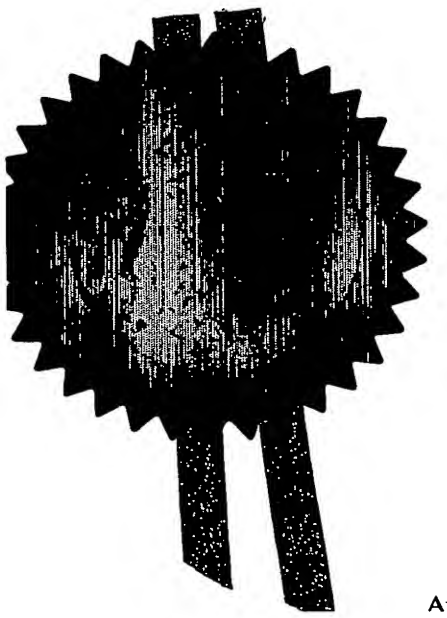
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed Andrew Gersey

Dated 7 May 2004

Patents Form 1/77

Patents Act 1977
(Rule 16)

The Patent Office

25APR03 E809679-1 000129
P01/7700 0.00-0309389.5

1/77

THE PATENT OFFICE
J
25 APR 2003
NEWPORT

25 APR 2003

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office
Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — 0300090

2. Patent application number
(The Patent Office will fill in this part) — 0309389.5

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)* — 8032310001 ✓

If the applicant is a corporate body, give the country/state of its incorporation — GB

4. Title of the invention

TRACHEOSTOMY DEVICE

5. Name of your agent *(if you have one)*

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)* — 1063304001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document.

Continuation sheets of this form	
Description	7
Claim(s)	
Abstract	
Drawing(s)	2 + 2D

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature J M Flint Date 24 APRIL 2003

12. Name and daytime telephone number of person to contact in the United Kingdom J.M.FLINT 020 8457 8220

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

e) *Once you have filled in the form you must remember to sign and date it.*

f) *For details of the fee and ways to pay please contact the Patent Office.*

TRACHEOSTOMY DEVICE

This invention relates to tracheostomy devices.

A tracheostomy is used to enable direct access for breathing gases into the trachea through a surgically-made opening in the throat. The airway into the trachea is usually maintained with a tracheostomy tube. The tracheostomy tube has a patient end angled so that its axis is directed generally caudally along the trachea. The tube is bent along its length so that the machine end emerges through the tracheostomy and is terminated by a coupling and a flange to which a strap is secured. The strap extends about the neck of the patient and is used to hold the tube in position. Tracheostomy tubes often have an inflatable cuff close to the patient end that seals with the inside of the trachea, so as to confine gas flow to the bore of the tube. Tracheostomy tubes may have fenestrations above the cuff to allow some air flow to the larynx and thereby enable the patient to speak.

Tracheostomy tubes have been used satisfactorily for many years. However, they do suffer from a number of disadvantages. First, during use, secretions build up on the inside of the tube, which provide a site for the accumulation of bacteria. Release of these secretions into the respiratory passages is thought to be associated with a high prevalence of pneumonia infection in ventilated patients. For this reason, tracheostomy tubes must be carefully cleaned regularly. Alternatively, the tube may have a liner or inner cannula that is periodically removed and disposed of. These inner cannula have their own problems, such as in reducing the bore through the tracheostomy tube. The maintenance necessary for tracheostomy tubes is an additional burden on hospital staff and requires the establishment of procedures to ensure

that the maintenance is carried out correctly and routinely. Another problem with tracheostomy tubes is that they need to be secured to the neck by means of a strap or the like. This makes the tubes more conspicuous, which is a particular problem to patients where the tube needs to be in place for prolonged periods. A further problem arises with cuffed tubes in that secretions produced in the upper part of the trachea, above the cuff on the tube, tend to collect on the inflated cuff, between the outside of the tube and the trachea. Although some of these secretions can be removed by suctioning, it is difficult to remove all secretions from the confined space between the tube and trachea.

It is an object of the present invention to provide an alternative tracheostomy device.

According to one aspect of the present invention there is provided a tracheostomy device comprising a tubular member adapted to provide a gas passage into the trachea through an opening in neck tissues, external means for retaining the tubular member with the external surface of the neck around the opening and internal means for retaining the tubular member with the internal surface of the trachea around the opening.

According to a second aspect of the present invention there is provided a tracheostomy device including a tubular member adapted to provide a gas passage into the trachea through an opening in neck tissues and sealing means adapted to seal the trachea at a location above the opening.

The device may include a suction passage extending from the sealing means externally by which secretions that collect on the sealing means can be removed.

According to a third aspect of the present invention there is provided a tracheostomy device comprising a tubular member adapted to provide a gas passage into the trachea through an opening in neck tissues, means for retaining the tubular member with the internal surface of the trachea around the opening and for sealing the trachea at a location above the opening.

According to a fourth aspect of the present invention there is provided a method of enabling flow of gas to a patient's trachea including the steps of forming a gas passage through neck tissue into the trachea and sealing the trachea against gas flow at a location above the gas passage.

A tracheostomy device according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side elevation view of the device in use;

Figure 2 is a sectional side elevation view of a part of the device to a larger scale;

Figure 3 is a end view of the patient end of the part shown in Figure 2;

Figure 4 is a sectional side elevation view of a part of an alternative device;

Figure 5 is an end view of the patient end of the part shown in Figure 4;

Figure 6 is a cross-sectional view of a part of another alternative device; and

Figure 7 is a sectional side elevation view of a further alternative device in use.

With reference first to Figures 1 to 3, the device comprises two components namely a tubular component 1 providing an airway into the trachea 2 and a seal 3 preventing flow of gas along the trachea.

The tubular component 1 comprises a short, stiff, plastics tube 10 of circular section. The tube 10 extends through a tracheostomy opening 4 through neck tissue 5 overlying the trachea 2 and its length is selected so that its patient end 11 lies closely adjacent the surface 6 of the trachea and its machine end 12 lies closely adjacent the skin surface 7.

Both the machine end 12 and the patient end 11 have some form of retaining means 13 and 14 respectively to prevent displacement of the tube 10. The external retaining means at the machine end 12 takes the form of a fixed circular flange 13 projecting radially outwardly and abutting the skin surface 7 around the opening 4. The flange 13 may be clear or skin-coloured to make it less conspicuous. The machine end 12 of the tube 10 may include a conventional anti-occlusion cap, a coupling for connection to a ventilation machine, a speaking valve, HME or the like (not shown).

The internal retaining means 14 may take various different forms. The form shown in Figures 1 to 3 comprises a single tab 15 of a stiff plastics material hinged at its rear end 16 with the patient end 11 of the tube 10 and having a fold line 17 midway along its length. A pull cord 18 is joined with the forward end 19 of the tab 15 and extends rearwardly through a lumen 20 within the wall of the tube 10. The pull cord 18 is terminated with a button 21 by which it may be gripped and the cord can be fixed in position by pulling it into a narrow slot 22 in the flange 13. The natural shape of the tab 15 is extending forwardly, longitudinally, to enable the tube 10 to be inserted in the opening 4. When the cord 18 is pulled, the forward end 19 of the tab 15 is pulled rearwardly, causing the tab to flex at its rear end 16 and at its fold line 17 so that it bends into a V shape with its midpoint being displaced outwardly so that tab is folded in half and projects outwardly. It will be appreciated that there could be more than one tab for additional security. To remove the tube 10, the cord 18 is released so that the tab 15 can straighten during withdrawal.

The seal 3 includes an annular sealing ring 30 shaped to extend laterally across the trachea 2 and to seal with the trachea around its edge. A web 31 extends within the ring 30 to close its centre. The ring 30 could be inflatable or it may be of a resilient foam or the like formed integrally with the web 31. The web 31 has a shallow funnel shape with its centre 32 located slightly below its edge 33. A flexible drainage conduit 34 extends downwardly from the centre 32 of the web 31 externally via the tube 10 and is terminated by a coupling and closure 35.

The seal 3 is located above the airway provided by the tube 10 into the trachea 2 so that gas cannot flow above the seal and is, therefore, confined to flow along the tube.

Secretions produced in the trachea 2 above the seal 3 will collect in the centre 32 of the web 31 and can easily be removed by applying suction periodically to the coupling 35 of the drainage conduit 34. Alternatively, the conduit 34 could be left open and connected to a suitable drainage receptacle. The conduit 34 could be used to enable the patient to speak, by supplying air to the conduit so that it flows to the trachea above the seal 3.

The short length of the tube 10, without any appreciable projection into the trachea 2, has several advantages. There is less accumulation of secretions so maintenance is greatly facilitated. There is less risk of blockage by obstructions within the tube 10 and there is no risk of blocking by contact with the carina. The tube 10 affords less resistance to gas flow than conventional, longer tubes. Also, the short tube 10 does not create any obstruction should surgery be needed within the trachea 2 just below the tracheostomy 4. The absence of a cuff contacting the trachea below the tracheostomy opening can be an advantage if there has been damage to the trachea in this region. Because the tube 10 can be securely retained by the internal and external retaining means, there is less need to use a strap to secure the external flange around the neck. This can help make the device less conspicuous than conventional tracheostomy tubes.

~~Various modifications are possible to the device. The tube could be adjustable in~~ length, such as by screw threading.

Many alternative forms of retaining means are possible. Figures 4 and 5 show a tube 10' with an inner retaining means provided by a rotatable tab 45 mounted on one end of a shaft 46 that extends outwardly through a lumen 47 in the wall of the tube. By rotating a

handle 48 on the external end of the shaft, the tab 45 can be swung from a first position where it projects inwardly (for insertion) to a second position where it projects outwardly (for retaining the tube).

Figure 6 illustrates a tube 10'' in four longitudinal sections 51 to 54 that are foldable with one another along four longitudinal hinge lines 55 to 58 and that has fixed flanges 59 at both ends. The tube 10'' is collapsed to a smaller cross-section for insertion so that the inner flanges 59 do not hinder this. The tube 10'' is then opened out within the tracheostomy opening so that the flanges 59 at the ends engage the surface of the trachea and the skin respectively.

Figure 7 illustrates an alternative device where the inner retaining means is provided by the same component that effects the sealing. A deformable sealing ring 60 located above the tube 10''' has an annular extension 61 projecting downwardly and encircling the patient end of the tube. This locates against the trachea surface around the patient end of the tube.

The invention could be modified in many other ways. For example, the seal above the tracheostomy opening could be used with a conventional, uncuffed tracheostomy tube. Alternatively, in some situations the tube with its internal and external retaining means might not require the seal above the tracheostomy opening.

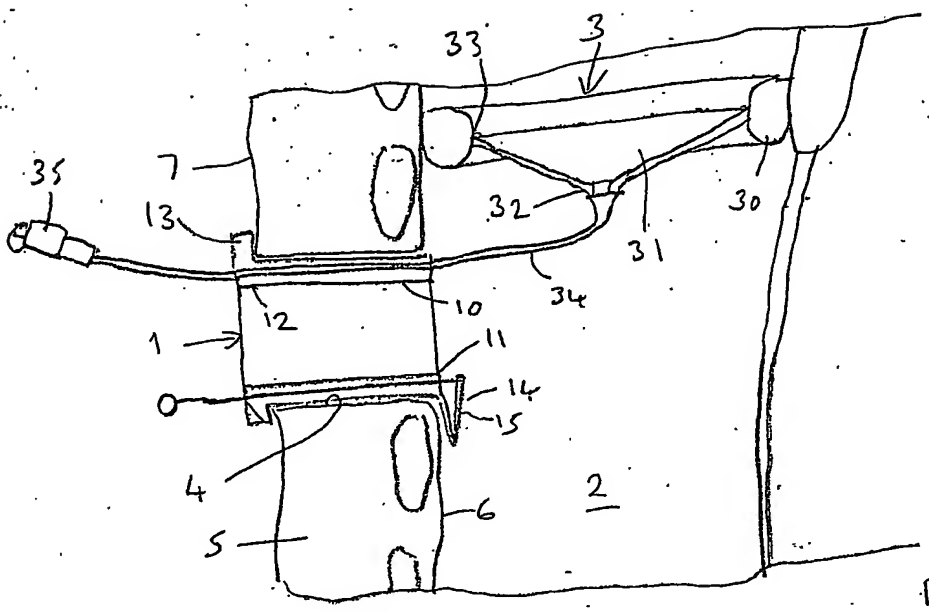


FIG. 1

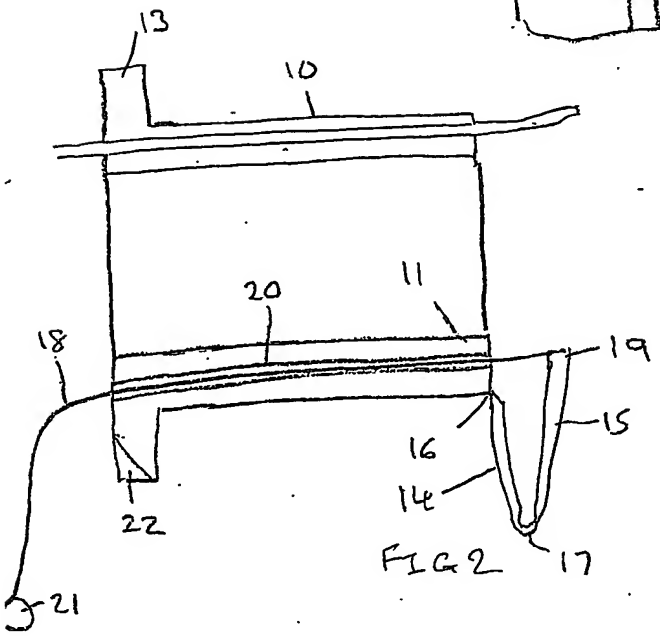


FIG 2

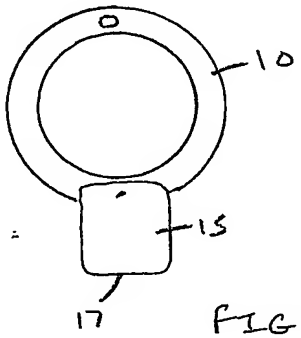


FIG 3

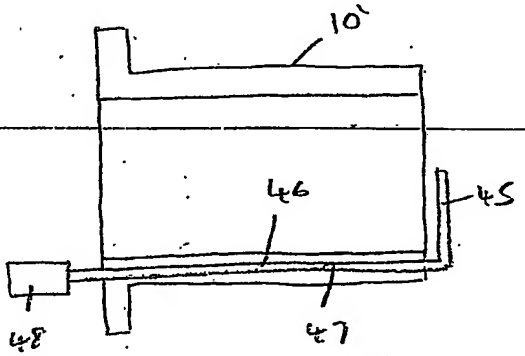


FIG 4

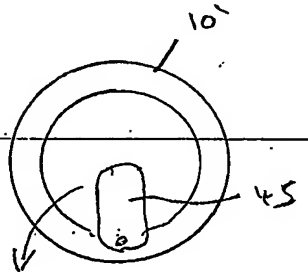


FIG 5

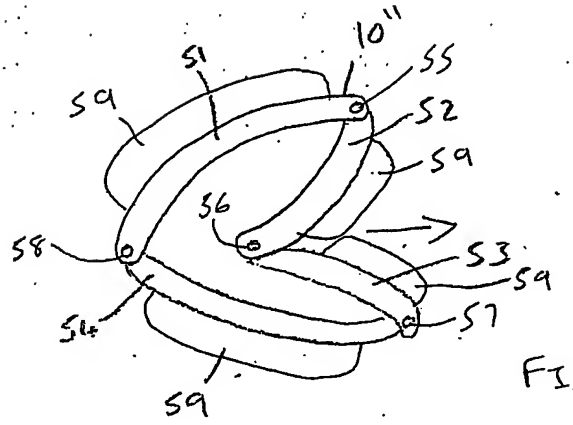


FIG. 6

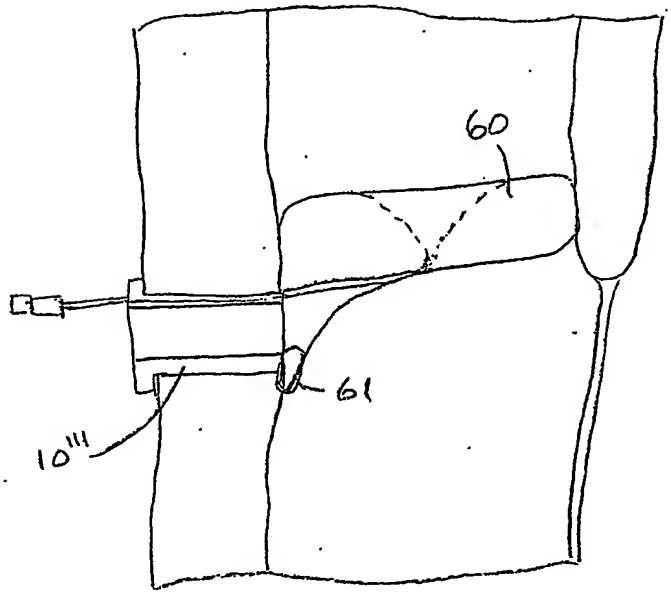


FIG. 7